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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/356,322	11/24/1998	TIDHAR DARI SHALON	STFD:009--1	7679

7590 10/01/2002

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EXAMINER
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MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/01/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/356,322

Applicant(s)

Shalon et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 18, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7-40 is/are pending in the application.
- ~~4a) Of the above, claim(s) 1-6 have been canceled.~~ ~~is/are withdrawn from consideration.~~
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jun 18, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 24 & 25
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The request, filed 6/18/02, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/356,322 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' arguments, filed 6/18/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a new PTO Form 948 is mailed herewith due to informalities yet to be corrected on the new Drawings, filed 6/18/02. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claims 7-20, 34, 35, 38, and 39 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above listed instant claims contain NEW MATTER in that there is no written basis for the generic phrase "each region in the microarray is essentially free of cross-contamination with...". Applicants point to support firstly in the instant specification on page 11, line 26, through page 12, line 12. Consideration of this passage reveals that it is devoid of any mention of whether cross-contamination occurs or not or how much or freedom thereof. Consideration of the other citations also failed to reveal written basis for the above phrase. Applicants recited a passage from page 12 of a great-grandparent application regarding the depositing of a bead one at a time etc. in page 6 of their remarks and then alleged that the preclusion of cross-contamination is inherent in such a recitation. In response, there is nothing seen in said recitation regarding the presence or absence of cross-contamination from "known" amounts, or "selected" solutions at "selected" regions to form a "desired" microarray. These recitations only define what is deposited at each region of the array and not anything about the quality of deposition or lack thereof. There is no recitation that relates to cross-contamination or lack thereof. For example, one could explain the throwing of a "known" amount of a "selected" paint in

a bucket at a "selected" wall region for the formation of a "desired" paint pattern without any statement as to whether the paint splatters or not. The paint splattering would rely on various characteristics of the paint itself and not on the "known" amount etc. as noted above.

PRIORITY FOR THE INSTANT CLAIMS:

Due to the remaining issue as summarized above regarding NEW MATTER the only instant claims which can be granted priority to the earliest parent of 6/17/94 are claims 21-33, 36, 37, and 40.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 7-20, 34, 35, 38, and 39 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Lipshutz et al. (P/N 6,013,440).

This rejection is reiterated below and maintained from the previous office action, mailed 12/18/01, as the above priority determination still supports this rejection based on this prior art.

Claims 7, 11-15, 17, 18, 20, and 34 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Dehlinger (P/N 5,723,320).

This rejection is reiterated below and maintained from the previous office action, mailed 12/18/01, as the above priority determination still supports this rejection based on this prior art.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 7-40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pirrung et al. (WO 90/15070).

Pirrung et al. describes the preparation of high density arrays of receptor units which are listed as options on page 11, lines 4-24, inclusive of polynucleotide as an option. The regions on which these are immobilized in Pirrung et al. may be of a variety of shapes including circular, elliptical, etc. as described on page 14, lines 9-16. These regions are formed of substantially pure polymers, as noted on page 14, lines 18-26, which suggests that the formation of these regions occurs in a process which is essentially free of cross-contamination, as also instantly claimed. On page 28, lines 20-36, these essentially free of contamination regions with substantially pure sequences thereon are deposited optionally in a broad range of numbers and densities which are clearly inclusive of the number of regions as well as the instantly claimed densities. For example, 1,000 to 100,000,000 sequences may be present on a single substrate. If the substrate had a surface area as cited on page 28, line 22, as 1 centimeter squared, the density would be 1,000 to 100,000,000 polymer sequences per square centimeter. The substrate may be glass, non-porous, etc. as in flat glass as noted on page 20, lines 6-33, as also instantly claimed. Hydrophobicity of the surface as in instant claim 26 is cited in the reference in the bridging paragraph between pages 21 and 22 due to linkers on the surface to which the polynucleotides are attached. These linkers may be of a variety of types including polycationic as summarized

on pages 22-23 and in instant claims 16 and 36. The receptor polynucleotides are immobilized covalently by reactions summarized in the reference on pages 15-18 with covalent bonds shown, for example, on page 17, line 25, to the polymer receptor, such as a polynucleotide. Additionally, it is noted that non-covalent immobilization of nucleic acids may also occur via the receptor polynucleotide binding to immobilize sample nucleic acids as discussed in the reference on page 19, lines 13-23. Such nucleic acids are well known to be optionally oligomers as well as gene length, or even a whole chromosome of millions of bases in length. Thus, clearly immobilization of sequences of 50 or more bases as in claim 7 is included as being suggested and motivated by the reference. It is noted that the instant claims are directed to a substrate which has a microarray of DNA, polynucleotide, sequences which is a product by process claim which is reasonably deemed to result in circular regions in the size and density range as in the reference albeit the reference attaching the polynucleotides in a different manner than by volumetric deposition. Thus, the microarray of the reference and that as instantly claimed are reasonably interpreted as being the same in the final microarray product.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to prepare a microarray substrate as instantly claimed as one clearly



suggested and motivated option of receptor array in the reference. It is noted that clearly defined species within a generic reference are deemed to be suggested and motivated as being obvious under 35 U.S.C. § 103(a).

It is additionally noted that product by process claims may cite analyses which are not specifically in a reference but are reasonably expected to be a characteristic of the product of a reference. Such characteristics are cited in instant claims 35, 38, and 39 as abilities to measure particular expression levels. The intensity related to the amount of hybridized sample polynucleotide is fully expected to be equally readable in the Pirrung et al. microarrays as in those as instantly claimed because they are the same species of arrays. In such cases, however, the burden to distinguish the instantly claimed product over that of the reference is shifted to applicants. See the following paragraph regarding legal support for this shifting of burden.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess

characteristic relied on" (205 USPQ 594, second column, first full paragraph).

No claim is allowed.

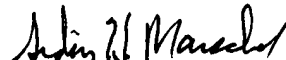
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 27, 2002

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER